UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Milanesi et. al v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION & ORDER NO. 32

This matter comes before the Court on (i) C.R. Bard, Inc. ("Bard") and Davol Inc.'s ("Davol") (collectively, "Defendants") Motion *in Limine* ("MIL") No. 2 to Exclude Evidence and Argument Concerning Material Safety Data Sheets and Technical Data Sheets, (ECF No. 189) (hereinafter "Defendants' MIL No. 2"), which Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi ("Plaintiffs") oppose, (ECF No. 266), and (ii) Plaintiffs' MIL No. 2 to Exclude Reference to Reason for Warnings on Any MSDS and Technical Data Sheets, (ECF No. 213) (hereinafter "Plaintiffs' MIL No. 2"), which Defendants oppose. (ECF No. 234.)

For the reasons stated herein, the Court **DENIES IN PART** Defendants' Motion *in Limine* No. 2 (ECF No. 189) but **RESERVES JUDGMENT** as to the admissibility of the Pro-fax 6523 Material Data Safety Sheets ("MSDS") released after Mr. Milanesi's July 11, 2007 implant. The

Court **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' Motion *in Limine* No. 2. (ECF No. 213.)

I.[1]

The Milanesi's case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts here are as follows: The Ventralex large hernia patch is a prescription medical device used for umbilical and small ventral hernia repairs. One side of the device contains polypropylene mesh, while the other contains an ePTFE layer. When the large Ventralex was released in 2006, it used polypropylene mesh derived from a polypropylene resin known as Pro-fax 6523, which is manufactured by (what is now) LyondellBasell. In 2006, LyondellBasell's predecessor, Basell, sold Pro-fax 6523 to Red Oak Sales Company, which then converted it into polypropylene monofilament. Bard then purchased this polypropylene monofilament and converted it to Ventralex mesh.

On July 11, 2007, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

resection. Dr. Karanbir Gill, Mr. Milanesi's surgeon, used a large Ventralex patch to repair Mr. Milanesi's injury. Ten years later, on May 25, 2017, Mr. Milanesi was diagnosed with a recurrent entrapped or obstructed ventral incisional hernia. He received emergency surgery the next day. On June 1, 2017, Mr. Milanesi returned for another emergency surgery to remove a high-grade post-operative bowel obstruction caused by "adhesions in the right lower quadrant." Afterwards, Mr. Milanesi developed a recurrent abdominal wall hernia near his previous surgery sites.

Plaintiffs allege that the Mr. Milanesi's injuries resulted from the implantation of the large Ventralex hernia patch. Specifically, they allege that Mr. Milenesi's Ventralex Large Hernia Patch "buckled," causing its bare polypropylene side to adhere to his bowels, leading, in turn, to a high-bowel blockage and, eventually, multiple hospitalizations. Plaintiffs make three principal allegations to support their claim: (i) that "polypropylene resin oxidatively degrades in vivo," (ii) that the ePTFE layer of the large Ventralex device contracts more than the polypropylene, which in combination with the too-weak memory coil ring causes the device to fold or buckle or "potato chip," and (iii) that the ePTFE layer was prone to infection because of the ePTFE layer's small pore size, which is big enough for bacteria to grow in, but too small for white blood cells to enter to intercept the bacteria.

Plaintiffs allege that Defendants knew of the above risks and marketed and sold the Ventralex device without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages.

In the years before and after Mr. Milanesi's July 11, 2007 implant, at least two companies that manufactured the resin that ultimately wound up in Defendants' hernia mesh devices issued

various documents—known as Material Safety Data Sheets ("MSDS") or Technical Data Sheets ("TDS")—that specifically warned against the use of their respective product in medical implants. Defendants believe Plaintiffs will attempt to use those documents at trial to demonstrate that Defendants allegedly knew of the Ventralex's polypropylene-related health risks. Accordingly, Defendants now seek to exclude those documents from trial under Federal Rules of Evidence 402, 403, and/or 802. (ECF No. 189.) Plaintiffs, conversely, seek to prevent Defendants from using certain evidence to explain *why* the polypropylene resin manufacturers that created the documents at issue decided to warn against the use of their product in medical devices. (ECF No. 213.)

II.

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig*., 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence in advance of trial in order to avoid delay and ensure an evenhanded and expeditious trial." *In re E.I. du Pont De Nemours & Co.*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and

potential prejudice may be resolved in proper context." *Ind. Ins. Co*., 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388. The denial, in whole or in part, of a motion *in limine* does not admit all evidence contemplated by the motion; it simply means that the court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence that is not relevant is inadmissible. Fed. R. Evid. 402. Additionally, under Federal Rule of Evidence 802, a court must exclude hearsay statements, unless provided otherwise by (i) a federal statute, (ii) the Federal Rules of Civil Procedure, and (iii) other rules prescribed by the Supreme Court of the United States. Fed. R. Evid. 802. A court may also exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III.

A. Defendants' MIL No. 2

1. MSDSs and TDSs

Federal regulations issued by the Occupational Health and Safety Administration (OSHA)

require manufacturers to create an MSDS (also known as a Safety Data Sheet, or "SDS") for each hazardous chemical that they use, produce, or import. [2] 29 C.F.R. § 1910.1200(g)(1). The purpose of this section, entitled "[h]azard communication," "is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees." *Id.* at § 1910.1200(a)(1). The purpose of the hazard communication is to protect the occupational safety and health of employees. *See id.* at § 1910.1200(a)(2). Manufacturers are required to "identify and consider the full range of available scientific literature and other evidence concerning the potential hazards" and to "classify" the hazards so that proper protective measures may be taken in the workplace. *Id.* at § 1910.1200(a)(2), (b)(1), (d)(1).

Separately, chemical materials manufacturers may also issue a TDS for the purchasers of their products. Generally, these documents—which are released at the manufacturer's discretion—are meant to provide the manufacturer's customers a summary of a product's composition, common methods of use, and chemical properties. They can also include relevant safety considerations.

2. The Documents at Issue

Defendants' MIL No. 2 exclusively relates to documents made by two polypropylene manufacturers: Phillips Sumika Polypropylene Company ("Phillips Sumika") and LyondellBasell. Both companies produce polypropylene resins that ultimately wound up in Defendants' line of hernia mesh products. Over time, each manufacturer issued documents that specifically caution against the use of those resins in medical implants. Those documents include: (i) Phillips Sumika's

[2] In 2013, the Occupational Safety and Health Administration amended 29 C.F.R. § 1910.1200(g)(1) to henceforth refer to MSDSs as SDSs. For ease of reference, the Court will refer to both types of documents as MSDSs.

2004 MSDS for Marlex Polypropylene, (*Johns v. C.R. Bard et al.*, Case No. 2:18-cv-1509 ("*Johns*"), ECF No. 175-1) (the "Marlex MSDS"), (ii) LyondellBasell's 2001 and 2007 MSDSs for Pro-fax 6523, (ECF Nos. 104-2, 104-4) (collectively, the "Pre-Implantation Pro-fax MSDSs"), as well as the 2013 and 2017 versions of the same document, (ECF Nos. 189-1 & 189-2) (collectively, the "Post-Implantation Pro-fax MSDSs"), and (iii) a TDS released by LyondellBasell's predecessor company, Basell, in 2006 (the "2006 TDS"). (ECF No. 104-3.) Defendants, for various reasons, argue that all of these documents are inadmissible under the Federal Rules of Evidence, and, thus, warrant exclusion from trial. (ECF No. 189.)

3. The Marlex MSDS

The Marlex MSDS contains the following disclaimer:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.
>
> Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.
>
> Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

(*Johns*, ECF No. 175-1.)

The Court addressed the admissibility of the Marlex MSDS in the first bellwether trial of this MDL, *Johns*. There, the plaintiff alleged, inter alia, that Defendants were aware of certain risks associated with the use of polypropylene-based mesh when the device at issue—the Ventralight ST—was implanted in the plaintiff. The plaintiff intended to use the Marlex MSDS' Medical Application Caution to support this contention. (*Johns*, ECF No. 183.) Defendants,

accordingly, sought to prohibit the admission of the Marlex MSDS, arguing (as they largely do here) that the document was (i) irrelevant given the nature of the plaintiffs' claims; (ii) unduly prejudicial; and (iii) inadmissible hearsay. (ECF No. 175.) None of those arguments was well taken by this Court, which found that the Marlex MSDS was both relevant and admissible for the purpose of demonstrating that Defendants knew, or had notice of, the Ventralight ST's polypropylene-related risks. (ECF No. 355.)

Here, Defendants' MIL No. 2 resuscitates (and attempts to distinguish) several of the arguments noted above. (ECF No. 189.) First, Defendants contend that the Marlex MSDS is irrelevant because (i) it does not relate to the resin that was actually used in the product at issue (the Ventralex), and (ii) "the specific type of polypropylene resin used in the mesh in the Ventralex has [nothing] to do with the [buckling] defect Plaintiffs allege caused Mr. Milanesi's injuries." (*Id.*) If the Court finds that the Marlex MSDS *is* relevant to any of Plaintiffs' claims, Defendants assert that it should still be barred from admission because it would be "prejudicial and potentially confusing to the jury." (ECF No. 189 at PageID #14176.) All of these arguments are unpersuasive.

i. Rule 402

The Court, as it did in *Johns*, first addresses Defendants' relevance arguments. Rule 401 provides a "liberal" "standard of relevance." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). Courts in "[t]his Circuit appl[y] an 'extremely liberal' standard for relevancy." *United States v. Collins*, 799 F.3d 554, 578 (6th Cir. 2015) (quoting *United States v. Whittington*, 455 F.3d 736, 738 (6th Cir. 2006)); *see also United States v. Pritchard*, 964 F.3d 513, 526 (6th Cir. 2020) ("Federal Rules are extremely permissive as to what evidence is relevant." (quoting *Wood v. Wal-Mart Stores E.*, 576 F. App'x 470, 473 (6th Cir. 2014))).

Here, Defendants first contend that there is "no evidence" which suggests that Bard was

aware of the cautionary language of the Marlex MSDS (which was issued in 2004) before Mr. Milanesi's 2007 surgery—and, thus, the document is irrelevant to the issue of notice. (ECF No. 189 at PageID #14176.) The Court disagrees. For one, there is the Marlex MSDS itself, which testimony indicates was readily available to Bard vis-à-vis Davol. (*See* Dep. of Stephen Eldridge, ECF No. 280-2) (noting that Davol regularly received "information from vendors that showed what the specs were for the polypropylene material")); (*see also* Dep. of Julia Babensee, ECF No. 87-3.) There is also testimony demonstrating that, as far back as 1997, Bard was aware of the risks posed by manufacturing devices that contained Marlex Polypropylene. (*See* Dep. of Roger Darois, ECF No. 87-6, at PageID #176.) Thus, Defendants' initial argument is not well taken.

Second**,** Defendants contend that, because the large Ventralex hernia patch was not made with Marlex Polypropylene, the Marlex MSDS is irrelevant to Plaintiffs' claims. This argument misses the forest for the trees. Here, Plaintiffs claim that Mr. Milanesi's injuries stemmed from the mesh component of the Ventralex device, which derived from Pro-fax 6523. They also claim that Defendants had notice of (i) the Ventralex's ability to expose polypropylene to a user's visceral tissue and (ii) the physical risks entailed by that exposure. (ECF No. 87 at #6589-6591.) Plaintiffs do not, however, contend that Defendants were notified of *only* the risks related to the implantation of Pro-fax 6523 in the human body. Rather, they focus on Defendants' awareness of the physical risks posed by the polypropylene chemical it contained.

Defendants' argument suggests they believe that, even if a sophisticated medical device manufacturer like Bard was notified that one of its hernia mesh products carried polypropylene-related health risks, it would have no reason to suspect similar problems in its *other* polypropylene-based hernia mesh products. The Court disagrees. If, as Plaintiffs contend, Defendants received notice of the polypropylene-related risks associated with the use of Marlex polypropylene in one

of their hernia mesh products, they would certainly have greater reason to suspect that their use of Pro-fax 6523 in the same fashion carried the same risks. *See* Fed. R. Civ. P. 401. Thus, on the facts given, the Court finds that the Marlex MSDS—and any notice Defendants had thereof before Mr. Milanesi's implant[3]—is relevant to the Plaintiffs' notice-related claims.

Finally, Defendants argue that the Marlex MSDS is irrelevant because "neither polypropylene in general nor the specific type of polypropylene resin used in the mesh in the Ventralex has anything to do with the defect Plaintiffs alleged caused Mr. Milanesi's injury." (ECF No. 189 at PageID #14177.) To that end, Defendants characterize Plantiffs' theory of causation to exclusively revolve around the "buckling" of the Ventralex—not the exposure of Mr. Milanesi's bowels to bare polypropylene. (*Id.*) Indeed, Defendants concede (as they did in *Johns*) that "[t]here is no dispute that *any* type of bare polypropylene mesh exposed to internal organs can result in injury because it is designed for tissue growth." (*Id.*) However, according to Defendants, "[n]one of Plaintiffs' experts" either (i) "opine[] that Mr. Milenesi's specific injuries were the result of the *type* of polypropylene resin use in the Ventralex" or (ii) "connect any MSDS or TDS to anything that happened to Mr. Milanesi." (*Id.*) (emphasis added). For these reasons, Defendants argue, the Marlex MSDS (and the rest of the documents covered in Defemdants' MIL No. 2) do not pass must under Rule 402.

The Court plainly disagreed with a nearly identical argument in *Johns*. (*See* ECF No. 355 at PageID #18759). Unsurprisingly, Defendants' second bite at the apple fares no better. It is true that Plaintiffs allege Mr. Milanesi's injuries were onset by the "buckling" of the Ventralex. But that is not the end of the story that Plaintiffs have repeatedly put forth. Indeed, they have alleged

[3] As discussed further on, the issue of post-surgery evidence as it relates to notice and the Plaintiffs' claim of a continuing duty to warn will be addressed in a later MIL Order.

multiple times throughout this litigation that, once the Ventralex "buckled," it exposed Mr. Milenesi's bowels to bare polypropylene, resulting in bowel erosion and fistulae. (*See* ECF Nos. 1 at PageID #13; 87 at PageID #6611.) They have also consistently alleged that Bard knew—or, at the very least, received notice—that its use of bare polypropylene could, once exposed to human tissue, lead to the Mr. Milanesi's stated injuries. (ECF Nos. 1 at PageID #6, 14, 24; 87 at PageID #6591-99.) The Marlex MSDS is one possible way that Plaintiffs can demonstrate the second allegation. That is why it is relevant. Defendants attempt to once again "ignore the latter links in the chain of causation" does not change that fact. (*See Johns*, ECF No. 355 at PageID #18759.)

ii. Rule 403

Next, the Court turns to Defendants' contention that Plaintiffs' use of the Marlex MSDS at trial would be "prejudicial and potentially confusing to the jury since Marlex resin was not used in the manufacture of the Ventralex device at issue in this case." (ECF No. 189 at PageID #14176.) Defendants also imply (as they did in *Johns*) that this confusion would be compounded by the fact the Marlex MSDS "lacks any basis in science and is disconnected from any *finished* hernia mesh device." (*Id.*) (emphasis in original). Accordingly, Defendants believe the Marlex MSDS should be excluded under Rule 403. Again, the Court disagrees.

To be clear, Plaintiffs may only use the Marlex MSDS for purposes of demonstrating that Defendants had notice of the risks associated with implanting polypropylene-based materials in the human body. In *Johns*, the Court found that a limiting instruction to the jury would sufficiently ward off any undue prejudice that could result from Plaintiffs' use of the Marlex MSDS for the exact same purpose. (*Johns*, ECF No. 355) (finding that "[a]ny risk of prejudice is mitigated with a limiting instruction explaining that the MSDS is only to be considered as evidence of notice and an instruction explaining the regulatory basis for the MSDS"). This was so regardless of the

document's scientific foundation. Accordingly, if Plaintiffs choose to use the Marlex MSDS at trial, the Court will issue a similar instruction to the jury directing it to consider the document only for the exclusive purpose of determining whether Defendants had notice of the risks associated with implanting polypropylene-based materials (such as Pro-fax 6523) in the human body before the Ventralex was implanted in Mr. Milanesi.

Accordingly, Defendants' Motion *in Limine* No. 2 is **DENIED IN PART.**

4. The Pre-Implantation Pro-Fax MSDSs

Notably, Defendants MIL No. 2 only raises arguments for the exclusion of the Marlex MSDS, the 2006 TDS, and the Post-Implantation Pro-fax MSDSs. (ECF No. 189.) Only in Plaintiffs' Response to Defendants MIL No. 2 are the Pre-Implantation Pro-fax MSDSs first mentioned. (ECF No. 266.) Nevertheless, Defendants, in responding to Plaintiff's MIL No. 2, took the opportunity to argue against the admission of the Pre-Implantation Pro-fax MSDSs. (*See* ECF No. 234 at PageID #15309.) For purposes of consistency, the Court will address those arguments here.

First, some background. In 2001, LyondellBasell's predecessor, Basell, released the original MSDS for Pro-fax 6523 (the "2001 Pro-fax MSDS"). (ECF No. 104-2.) The document did not appear to contain any statement that specifically warned downstream users not to use the material in medical implants. (*Id.*) It did, however, contain the following line:

> **STORAGE**: This product may react with strong oxidizing agents and should not be stored near such materials. Store boxes and bags of material in areas protected with automatic sprinklers.

(*Id.* at PageID #9125.)

In February of 2007, Basell released a revised version the 2001 Pro-fax MSDS (the "2007 Pro-fax MSDS"). (ECF No. 104-4.) This document, like its predecessor, did not contain any medical product-related warning. It was, however, revised to include the following disclaimer

under a section entitled "STABILITY AND REACTIVITY":

> **CONDITIONS TO AVOID**: Avoid contact with water. Keep aware from heat, sparks and flame. Avoid contact with strong oxidizing agents, strong alkaline and strong acid."

(ECF No. 104-4 at PageID #9138.)

Part of Defendants' argument against Plaintiffs' use of the Post-Implantation Pro-fax MSDSs at trial is that, prior to 2013, no Pro-fax 6523 MSDS "included any language regarding [its] medical use[.]" (ECF No. 189 at PageID #14178.) To undermine this contention, Plaintiffs point to the excerpts from the Pre-Implantation MSDSs copied above. (ECF No. 266 at PageID #16375-76.)

Plaintiffs' rebuttal, however, does not actually challenge Defendants' argument. Both excerpts highlighted above rather unambiguously relate to the storage of Pro-fax 6523—not the risks associated with using it in medical products. This obviously differs from the Medical Application Caution in the Marlex MSDS and the disclaimers in the Post-Implantations Pro-fax MSDSs. Thus, to the extent Plaintiffs seek to use the Pre-Implantation MSDS excerpts above for purposes of proving that Defendants had notice of the health risks associated with Pro-fax 6523, their argument is not well taken.

Separately, Plaintiffs suggest their intention to introduce the Pre-Implantation Pro-fax MSDSs for the purpose of proving the truth of the matter the documents jointly assert (*i.e.*, that Pro-fax 6523 "reacts strongly with oxidizing agents"). (*See* ECF No. 266 at PageID #16376, 16380.) Plaintffs argue that, once given an opportunity at trial to lay a proper foundation, such would be permitted under Rule 803(18)—also known as the Learned Treatise exception. *See* Fed. R. Evid. 803(18).

The Court confronted an identical argument concerning the Marlex MSDS in *Johns*. (*See Johns*, ECF No. 355, at PageID #18760.) There, the Court first noted that Rule 803(18)

> provides that "[a] statement contained in a treatise, periodical, or pamphlet" is admissible if "the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination" and "the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice."

(*Id.* at PageID #18760-61.) Subsequently, the Court determined that the *Johns* plaintiff "has not established the [Marlex] MSDS as a reliable authority that Marlex polypropylene should not be used in permanent implants in the body, *nor can he*." (*Id.* at PageID #18761) (emphasis added). This was because of Rule 803(18)'s express notation that any purported "learned treatise" should be "written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy, with the reputation of the writer at stake." Fed. R. Evid. 803(18) advisory committee's note; *see also* 30B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 6938 (2020 ed., West Apr. 2020 update) (noting that Rule 803(18) "is not a vehicle for the introduction of any and all reference sources"). The Marlex MSDS—which was written by Phillips Sumika to comply with federal work safety regulations—could not, by its very nature, satisfy these threshold criteria. (*Id.*)

So too here. As with the Marlex MSDS, the Pre-Implantation Pro-fax MSDSs were written by a polypropylene manufacturer (here, Basell) to comply with federal regulatory workplace standards. They were definitively *not* written "primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy, with the reputation of the writer at stake." That is why they do not satisfy Rule 803(18).

To that end, the Court **GRANTS** Defendants request to prevent Plaintiffs from using the Pre-Implantation Pro-fax MSDS excerpts noted above at trial.

5. The Post-Implantation Pro-fax MSDSs and the 2006 TDS

Much of Defendants MIL No. 2 seeks to prevent Plaintiffs from using the Post-Implantation Pro-fax MSDSs and the 2006 TDS at trial. Unlike the Pre-Implantation Pro-fax

MSDSs, these document all contain specific warnings that caution downstream users of Pro-fax 6523 not to use the substance in medical implants. (ECF Nos. 104-3, 189-1, 189-2.) Defendants argue that these documents should be excluded from trial because they are irrelevant, unduly prejudicial, and constitute inadmissible hearsay. (ECF No. 189.)

i. Rule 402

Defendants contend that the Post-Implantation Pro-fax MSDSs and the 2006 TDS are irrelevant because (i) they do not relate to Plaintiffs' theory of causation or the injuries Mr. Milanesi suffered, (ii) they do not have a scientific basis, nor has Plaintiff produced expert testimony that specifically states Pro-fax 6523 is "not suitable for implantation in the human body," (iii) Plaintiffs have not demonstrated that Defendants were aware of the 2006 TDS, and (iv) the Post-Implantation Pro-fax MSDSs—which were created well after Mr. Milanesi's July 11, 2007 implant—cannot support Plaintiffs' notice-based claims. (*Id.* at PageID #14181-84.)

Notably, the Court has ordered the parties to provide supplemental briefing that touches upon Defendants' fourth argument. (Order for Suppl. Br. on Continuous Duty to Warn Issue, ECF No. 283.) That briefing has yet to conclude. Thus, with respect to the Post-Implantation MSDSs, the Court will only address Defendants' first three relevancy arguments below.

The 2006 TDS contains the following statement under the heading "**NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS**":

> Unless specifically indicated, the grades mentioned are not suitable for applications in the pharmaceutical/medical sector, particularly: (A) in any commercial or developmental application which is intended for contact with human internal body fluids or body tissues, regardless of the length of time involved . . .
>
> Date of Release: 08 May 2006[.]

(ECF No. 104-3 at PageID #9134.)

Similarly, the 2013 Pro-fax MSDS includes the following statement under a caption

entitled "DISCLAIMER":

> CAUTION DO NOT USE EQUISTAR CHEMICAL, LP MATERIALS IN APPLICATIONS INVOLVING IMPLANTATION WITHIN THE BODY; DIRECT OR INDIRECT CONTACT WITH THE BLOOD PATHWAY; CONTACT WITH BONE, TISSUE, TISSUE FLUID, OR BLOOD; OR PROLONGED CONTACT WITH MUCOUS MEMBRANES. EQUISTAR CHEMICAL, LP MATERIALS ARE NOT DESIGNED OR MANUFACTURED FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES. EQUISTAR CHEMICALS, LP WILL NOT PROVIDE TO CUSTOMERS MAKING DEVICES FOR SUCH APPLICATIONS ANY NOTICE, CERTIFICATION OR INFORMATION NECESSARY FOR SUCH MEDICAL DEVICE USE REQUIRED BY FDA REGULATION OR ANY OTHER STATUTE. . . .
>
> Information is correct to the best of our knowledge at the date of the MSDS publication.
>
> The information on this MSDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, expressed or implied, regarding its correctness. Some information presented and conclusions drawn herein are from sources other than direct test data on the substance itself. . . .

(ECF No. 189-1 at PageID #1418.)

Likewise, the 2017 Pro-fax MSDS specifies on its first and second-to-last page that the use of Pro-fax 6523 is prohibited in "FDA Class III medical devices." (ECF No. 189-2 at PageID #14201, 14213.)

Defendants first contend that all of these disclaimers are irrelevant because they do not relate to Plaintiffs' theory of causation. (ECF No. 189 at PageID #14181.) Specifically, Defendants argue that Plaintiffs do not "claim[] Mr. Milanesi's injuries were caused by the type of polypropylene resin used in the Ventralex," but, instead, that his injuries stem from the alleged "buckling" of the Ventralex device. (*Id.* at PageID #14181-82.) In support, they highlight the fact that "Dr. Krpata, Plaintiffs' only case-specific expert . . . offered no opinion that the type of polypropylene used in the Ventralex was the cause of Mr. Milanesi's injuries." (*Id.* at PageID #14182.)

As noted above, Defendants' characterization of Plaintiffs' causation theory argues only one side of the same coin, sidestepping the central fulcrum of Plaintiffs' story: that, *after* the Ventralex "buckled," Mr. Milanesi's bowels were exposed to bare polypropylene, resulting in "bowel adherence, erosion, and infection." (ECF No. 87 at PageID #6591.) The testimony of Dr. Krpata supports this theory. (Dep. of David. M. Krpata, M.D., ECF No. at p. 8, 15, 28-29.) And Defendants have already conceded that the only polypropylene resin used in the Ventralex was Pro-fax 6523. (ECF No. 87-4.) Accordingly, the presence of Pro-fax 6523 in the Ventralex is certainly relevant to Plaintiffs' theory of causation.

Defendants next contend that the Post-Implantation Pro-fax MSDSs and the 2006 TDS are irrelevant because they were not written about "a finished medical device like the Ventralex" and are not "based on any scientific testing or data." (ECF No. 189 at PageID 14183.) This is tantamount to an argument that Defendants mounted in *Johns*. (*See* ECF No. 355 at PageID #18759) ("Next, Defendants contend that the MSDS is irrelevant to the finished medical device and is not based on any scientific research.") There, the Court found that:

> [t]he allegedly dangerous characteristics of a component of a device are certainly relevant to the question of whether a finished device has dangerous characteristics. And Defendants' argument about a lack of scientific basis for the Medical Application Caution does not render the statement in the MSDS irrelevant. Indeed, Defendants cite no on-point authority for this proposition. Instead, they cite cases dealing with the reliability of scientific expert testimony, which is a different admissibility question than relevance.

(*Id.*)

Yet again, Defendants have not provided any "on-point authority" for their argument, choosing instead to copy and paste the same exact footnote of cases that the Court discounted above. (*See Johns*, ECF No. 175 at PageID #10118 n. 7; ECF No. 189 at PageID #14183 n. 8.) So, yet again, the Court finds that Defendants exclusively and unpersuasively offer "'arguments about the weight of the evidence, not its relevance.'" (*Johns*, ECF No. 355 at PageID #18760)

(citing *United States v. Snyder*, 789 F. App'x 501, 512 (6th Cir. 2019).

Finally, Defendants argue that the 2006 TDS is not relevant because "there is no evidence that Bard had received this or any similar Pro-fax TDS prior to Mr. Milanesi's implant procedure such that it would have been on notice of anything contained therein." (ECF No. 189 at PageID #14179; *see also* ECF No. 299.) Defendants make two overall points in support. First, they note that Plaintiffs received the 2006 TDS from a third-party polypropylene monofilament producer called Shakespeare—which, during the years 2006 and 2007, did not supply Bard with any of the monofilament used in the Ventralex. Defendants further highlight the September 27, 2007 "print date" placed on the bottom right corner of the TDS, which, they contend, demonstrates that Shakespeare did not receive the document until several months after Mr. Milanesi's implant. Defendants conclude that these facts, taken together, demonstrate that "there is no evidence" that they received the 2006 TDS before the implantation of the Ventralex in Mr. Milanesi—and, thus, the TDS is entirely irrelevant to Plaintiffs claims. (ECF No. 299 at PageID #17196.)

The Court disagrees. Directly under the relevant disclaimer of the 2006 TDS is a "Release Date" that suggests the document was sent to (or, at the very least, published for) the users of Basell products on May 8, 2006—over a year before Mr. Milanesi's implant. Plaintiffs have adduced testimony from Stephen Eldridge, a Senior Manager of Davol's Research and Development team during 2006 and 2007, who, in direct reference to the 2006 TDS, stated (i) that Basell would have supplied the document to Davol and (ii) that Davol, in turn, "would have . . . kept [it] in a book somewhere" for its engineers' future reference. (ECF No. 280-2.) Defendants, for their part, note that "at no point did Mr. Eldridge testify that he had actual personal knowledge of [Davol] receiving the 2006 Pro-fax TDS at any time and certainly not prior to July 11, 2007." (ECF No. 299.) But such knowledge is not needed to render the TDS admissible, at least for the

purpose of demonstrating notice. Rather, it is enough for Plaintiffs to show (i) that the 2006 TDS was released by Basell prior to July 11, 2007, and (ii) during that time-period, Davol had the habit of receiving and storing TDSs like the one at issue. *See* Fed. R. Evid. 104(b). That is exactly what the testimony of Mr. Eldridge does.

Thus, at this juncture, the Court finds that the 2006 TDS is relevant to the issue of whether Bard had notice of the risks of using Pro-fax 6523 in a medical implant. (*See* ECF No. 104-3.)

Again, the parties have not concluded their supplemental briefing of an issue that directly relates to Defendants' fourth and final argument concerning the relevancy of the Post-Implantation MSDSs (*i.e.*, that they are irrelevant to the issue of notice because they both post-date Mr. Milanesi's July 2007 implant). Thus, the Court **RESERVES JUDGMENT** on (i) the relevancy of the Post-Implantation Pro-fax MSDSs and (ii) the rest of Defendants arguments related to the Post-Implantation MSDSs (*i.e.*, that they are barred under Rule 403 and 802).

The Court does not await any further briefing on an issue concerning the 2006 TDS. Thus, it addresses Defendants' remaining arguments against that document's admission below.

ii. Rule 403

Defendants argue that the 2006 TDS should be excluded because "any probative value" it contains "is substantially outweighed by the risks of jury confusion[,] unfair prejudice to Bard, and waste of time." (ECF No. 189 at PageID #14184.) The Court disagrees. The document's disclaimer expressly warns downstream handlers of Pro-fax 6523 not to use the substance in "any commercial . . . application which is intended for contact with human internal body fluids or body tissues, regardless of the length of time involved." (ECF No. 104-3.) Such clearly relates to permanent medical implants of the sort at issue. And, as discussed above, Plaintiffs have produced sufficient evidence that Bard (vis-à-vis Davol) received this document up to a year or more before

Mr. Milanesi's implant. This is clearly probative of Defendants' contention that Bard had notice of the risks of using polypropylene in the Ventralex before the device was implanted in Mr. Milanesi.

Defendants argue, however, that this probative value is "substantially outweighed" by the "significant risk" that the jury will take the 2006 TDS at face-value—that is, that they will "incorrectly consider it as evidence that the Ventralex is not suitable for permanent implant." (ECF No. 189 at PageID #14185.) Defendants additionally contend that, to combat this supposed confusion, they would be forced "to introduce extensive fact and expert evidence to minimize the prejudice it would cause," wasting "valuable trial time"—further justifying the TDS's exclusion under Rule 403. (*Id.*)

The Court, as noted above, addressed identical arguments in relation to Plaintiffs' use of the Marlex MSDS in *Johns*. *See supra* Part III.A.3.ii. There, the Court found that "any risk of [undue] prejudice" would be sufficiently mitigated by the issuance of a limiting instruction which advised the jury that (i) the Marlex MSDS was "only to be considered as evidence of notice," and (ii) the MSDS had a "regulatory basis." (*Johns*, ECF No. 355 at PageID #18762.) So too here. As discussed below, Plaintiffs may only use the 2006 TDS to demonstrate that Defendants had notice of the health risks associated with distributing a medical implant that contained polypropylene. *See infra*, Part III.A.5.iii. Accordingly, the Court finds that an instruction which advises members of the jury to only consider the 2006 TDS in that capacity is sufficient to ward off any risk of undue prejudice.[4] Defendants additional contention that they will need to spend "valuable trial time" giving context to the 2006 TDS is, accordingly, unpersuasive.

[4] Unlike with the Marlex MSDS, here it does not appear that Basell was legally compelled to issue the 2006 TDS. At this juncture, the Court does not feel that it is necessary to specify this in its limiting jury instruction.

iii. Rule 802

Plaintiffs suggest an intention to use the 2006 TDS to prove the truth of the matter asserted in the document's relevant disclaimer (*i.e.*, that Pro-fax 6523 is not suitable for use in medical implants). They argue that, in tandem with Mr. Eldridge's testimony, it is admissible for such a purpose under Rule 803(6), commonly known as the "Business Records" exception. (ECF No. 280 at PageID #16871.) The Court disagrees.

Rule 803(6) permits any "act, event, condition, opinion, or diagnosis" to be admitted to prove the truth of the matter asserted if:

> (A) the record was made at or near the time by — or from information transmitted by — someone with knowledge;
>
> (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;
>
> (C) making the record was a regular practice of that activity;
>
> (D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
>
> (E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid.803(6). Here, Mr. Eldridge's testimony suggests that Davol had the regular practice of both receiving and storing TDSs published by his employer's upstream suppliers. (ECF No. 299-1 at PageID #17204.) Mr. Eldridge, however, does not come close to suggesting that he or anyone else at Davol created the 2006 TDS. Nor does he convey that he knows when, if at all, Davol received the 2006 TDS. He merely suggests that Davol had the habit of receiving and storing documents *like* the 2006 TDS before Mr. Milanesi's implant. While this is enough to make the document relevant to the issue of whether Defendants had notice of the risks associated with the Ventralex's use of Pro-fax 6523, the same cannot be said for its admission under Rule 803(6),

which expressly requires the proponent of the record at issue to demonstrate that it was "made at or near the time by – or from information transmitted by – someone with knowledge." Fed. R. Evid. 803(6).

Plaintiffs do not argue that any other Rule 803 exception applies to the 2006 TDS.[5] Thus, at this juncture, the Court finds that the document is not admissible for the purpose of proving the truth of the matter asserted by its disclaimer.

6. **Conclusion**

Accordingly, the Court **DENIES IN PART** Defendants' Motion *in Limine* No. 2, and **RESERVES JUDGMENT** as to the admissibility of the Post-Implantation Pro-fax MSDSs. The Court **GRANTS** Defendants request to exclude the Pre-Implantation Pro-fax MSDSs as set forth in their Opposition to Plaintiffs' Motion *in Limine* No. 2.

B. Plaintiffs' MIL No. 2

Plaintiffs, in their MIL No. 2, seek to prevent Defendants from any "use or reference to certain evidence relating to" the rationales that Phillips Sumika and LyondellBasell had for including any specific warning statement on an MSDS or TDS that is introduced at trial. (ECF No. 213.) They make this argument largely pursuant to the Court's *in limine* determination in *Johns* that Defendants could not have various non-Phillips Sumika employees testify why Phillips Sumika added the Medical Application Caution to the Marlex MSDS. (*See Johns*, ECF No. 355 at PageID # 18762-65.)

The *Johns* plaintiff specifically sought to exclude the testimony of Frank Zekrzewksi, a former employee of Chevron Phillips Chemical Company ("Chevron Phillips"), as well as Roger

[5] In the Opposition to Defendants MIL No. 2, Plaintiffs argue that "the MSDS sheets" qualify for admission under Rule 803(18). If Plaintiffs intended this argument to extend to the 2006 TDS, their position is not well taken. This is because the 2006 TDS—like the Marlex MSDS—does not, by its very nature, appear to satisfy the baseline criteria of a "learned treatise." *See supra*, Part III.A.3.ii.

Darois, the former Vice President of Research and Development at Davol, Inc., under Federal Rule of Evidence 602. *See* Fed. R. Evid. 602 (requiring lay witnesses to have "personal knowledge" for all matters they testify to). Both of these individuals, in their respective depositions, testified that Phillips Sumika added the Medical Application Caution strictly out of concern for litigation—meaning, effectively, that the warning had no basis in scientific fact. (*Johns*, ECF No. 234.) This is the testimony that the *Johns* plaintiffs sought to exclude under Rule 602. The Court, largely agreeing with the *Johns* plaintiff's position, held the following:

> As a preliminary matter, the intent behind Chevron Phillips's or Phillips Sumika's inclusion of the Medical Application Causation is irrelevant. Because the MSDS is not admissible for the truth of the matter asserted, the actual reason for including the statement has no bearing on this litigation. Therefore, Zakrzewski's testimony is irrelevant because it is only offered to demonstrate Chevron Phillips's or Phillips Sumika's intent. (ECF No. 258 at PageID #13611–15.) There is thus no need to address Plaintiff's arguments regarding Zakrzewski's lack of personal knowledge or reliance on hearsay as a Federal Rule of Civil Procedure 30(b)(6) designee. However, what Defendants understood to be Chevron Phillips's and Phillips Sumika's intent based on what Defendants knew and observed at the time and whether that belief was reasonable is relevant to whether Defendants' conduct was reasonable under the circumstances or negligent. Thus, it is crucial to determine if there is evidence of when Defendants knew or believed that the MSDS was modified to include that statement as a result of the threat of litigation, rather than bona fide safety concerns about the use of Marlex within the human body.
>
> . . .
>
> At this time, it appears that Darois lacked personal knowledge of why Chevron Phillips or Phillips Sumika included the Medical Application Caution. Federal Rule of Evidence 602 provides that witnesses may only testify regarding matters of which they have personal knowledge. Fed. R. Evid. 602. This rule extends to Federal Rule of Civil Procedure 30(b)(6) designees, including Darois. *Mays v. LaRose*, 951 F.3d 775, 789–90 (6th Cir. 2020). Although a direct statement to Darois by Chevron Phillips or Phillips Sumika is unnecessary, Darois must still have some basis for his inferred understanding of why the Medical Application Caution was included. Here, Darois points to conversations in 1997 in his declaration, as well as deposition testimony from transvaginal mesh cases in 2014. But it is quite an extrapolation from a 1997 conversation to determine that an alteration to the MSDS in 2007 was related to a decade-old conversation about general litigation trends. And it is pure speculation to infer from the 2014 testimony that the Medical Application Caution was added due to litigation concerns simply. The testimony simply confirms why the statement was not added—confirmatory

> scientific research. Darois even states that neither Chevron Phillips nor Phillips Sumika ever contacted Defendants about the Medical Application Caution or otherwise. Defendants do not identify any other basis from which Darois could infer that the Medical Application Caution was added to address potential litigation. (ECF No. 258 at PageID #13615–16.)
>
> For these reasons, Plaintiff's Motion in Limine No. 2 is granted. If Darois or other witnesses have other bases upon which to base their testimony that Defendants believed the Medical Application Caution was added due to litigation concerns, then at trial the witnesses will be questioned outside of the jury's presence to determine whether the witnesses have personal knowledge as required by Rule 602. Otherwise, such testimony is inadmissible for lack of foundation.

(*Johns*, ECF No. 355, PageID #18762-65.)

Here, Plaintiffs effectively seek to keep out the same type of testimony. (ECF No. 234.) Unlike in *Johns*, however, they do not single out the testimony of any specific witness for exclusion. (*Id.*) Instead, they seek a blanket order that prohibits Defendants from offering evidence that even references the reason why Phillips Sumika or LyondellBasell included a warning on their respective MSDSs, as well as the disclaimer on the 2006 TDS. (*Id.*) This the Court will not do. *See Sperberg*, 519 F.2d at 712 ("Orders *in limine* which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise.").

Even so, the Court notes that its ruling in *Johns* remains applicable. That is, to the extent Defendants seek to introduce testimony (*e.g.*, that of Mr. Zakrzewski) which goes to Phillips Sumika's actual intent in adding the Medical Application Caution to the Marlex MSDS, such testimony is irrelevant and inadmissible. *See* Section III.A.3., *supra* (noting that the only permissible purpose for which the Marlex MSDS can be introduced is to prove Defendants' notice of the risks of inserting polypropylene-based materials into the human body). The same rationale would apply to identical testimony related to LyondellBasell's reasoning for the 2006 TDS disclaimer.

Nevertheless, here, as in *Johns*, evidence of (i) the time at which Defendants potentially became aware of the Medical Application Caution and/or the 2006 TDS and (ii) Defendants' *perception* of the intent behind the warnings on those documents *is* relevant to Plaintiffs' claims. (*See Johns*, ECF No. 355 at PageID #18763) ("[W]hat Defendants understood to be Chevron Phillips's and Phillips Sumika's intent based on what Defendants knew and observed at the time and whether that belief was reasonable is relevant to whether Defendants' conduct was reasonable under the circumstances or negligent."). Accordingly, the Court agrees with Defendants' contention that "[a]ny testimony by Bard witnesses regarding their understanding and interpretation of any MSDS or TDS would be squarely within the personal knowledge of such witnesses and relevant to the reasonableness of Bard's conduct." (*See* ECF No. 234 at PageID #15316.) Nevertheless, Defendants do not specify what testimony they would introduce for that purpose. (*Id.*)

Thus, to the extent Defendants attempt to introduce witness testimony for the purpose of demonstrating Bard's "understanding and interpretation" of the Marlex MSDS and 2006 TDS, the Court, as in *Johns*, will question all relevant witnesses "outside of the jury's presence to determine whether [they] have personal knowledge as required by Rule 602." (*See Johns*, ECF No 355 at PageID #18763.) So too will it evaluate all non-testimonial evidence that is introduced for the same purpose.

Accordingly, Plaintiffs' Motion *in Limine* No. 2 is **GRANTED IN PART** and **DENIED IN PART**.

IV.

For the reasons set forth above, Defendants' Motion *in Limine* No. 2 (ECF No. 189), the Court **DENIES IN PART** Defendants Motion *in Limine* No. 2, (ECF No. 189), and **RESERVES**

JUDGMENT on the issue of whether the Post-Implantation Pro-fax MSDSs are admissible. The Court **GRANTS** Defendants' request to exclude the Pre-Implantation Pro-fax MSDSs. (ECF No. 234.) Finally, the Court **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' Motion *in Limine* No. 2. (ECF No. 213.)

Specifically, the Court **FINDS**:

1. The Medical Application Caution contained within the Marlex MSDS is relevant and admissible to the extent it is used to demonstrate that Defendants had notice of the risks of inserting polypropylene-based materials (such as the Ventralex) into the human body. It is inadmissible, however, to prove the truth of the matter asserted.

2. The Pre-Implantation Pro-fax MSDSs do not appear to contain any warning related to the medical use of Pro-fax 6523, and, thus, are irrelevant to the issue of notice. Because they do not satisfy Rule 803(18), the documents are also seemingly inadmissible to prove the truth of the matter they collectively assert (*i.e.*, that polypropylene reacts "strongly with oxidizing agents").

3. The 2006 TDS is admissible for the purpose of proving that Defendants had notice of the health risks associated with inserting polypropylene-based materials into the human body. It is not, however, admissible to prove the truth of the matter asserted under Rules 803(6) and 803(18).

4. Three of the four arguments that Defendants mount concerning the relevancy of the Post-Implantation MSDSs' are unpersuasive. The Court will evaluate Defendants' fourth argument—which concerns a medical device manufacturer's "continuous duty to warn" under Florida law—as well as the general admissibility of the documents once the parties' supplemental briefing on the continuing duty to warn issue concludes.

5. Evidence that is introduced to prove the actual intent behind the Marlex MSDSs' Medical Application Caution or the 2006 TDS is irrelevant to the issue of notice, and, therefore, inadmissible for that purpose.

6. Evidence that is introduced to prove when and how Defendants perceived the Marlex MSDSs' Medical Caution Application and the 2006 TDS is relevant to the reasonableness or negligence of Defendants in the context of this case. The Court will evaluate any such evidence that is introduced by the parties as it arises and outside of the presence of the jury.

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/13/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE